PRODUCT BULLETIN

Product(s): Fabius GS

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Subject: CLIC Absorber on the Fabius GS

We are currently investigating reports related to the usage of the CLIC absorber on the Fabius GS. Based on our preliminary analysis, we have concluded that the CLIC absorber creates a higher flow resistance than the standard absorber used on the Fabius GS.

We have identified low-flow (= fresh gas flow less than 1 L/min) anesthesia scenarios under which small amounts of gas will escape through the scavenger valve (during the expiratory phase) instead of flowing through the CLIC absorber and ultimately into the breathing bag. (Please take a look at the Virtual Fabius GS and study the gas flow during the expiratory phase.)

Depending on several factors such as the patient's lung compliance and airway resistance, as well as the ventilator settings and the fresh gas flow settings, the breathing bag of the Fabius GS might slowly collapse because of the gas volume escaping through the scavenger valve. Once the breathing bag is completely collapsed, the Fabius GS will compensate for the lack of fresh gas by entraining room air and displaying a "Fresh Gas Low" alarm message. The situation can obviously be remedied by increasing the fresh gas flow, but this is not an acceptable permanent alternative to customers who want to run low-flow anesthesia. Customers can, however, use this remedy should this situation occur perioperatively.

We are in the process of evaluating several alternatives regarding the Fabius GS scavenger valve. By increasing the 'cracking pressure' (= pressure threshold at which valve opens) of the scavenger valve above the resistance created by the CLIC absorber, we would force the expired gas to flow through the CLIC absorber and back into the breathing bag.

Increasing the 'cracking pressure' of the scavenger valve will, however, lead to a slight increase in intrinsic PEEP during Man/Spont operation of the unit. We are conducting tests to balance these effects against each other and will evaluate our designs within the next several weeks.

Please note that this is NOT an investigation into the safety of the Fabius GS. Our system maintains adequate ventilation by air entrainment and provides accurate and timely feedback on

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the possible lack of fresh gas. It is our intention to optimize the low-flow performance of the Fabius GS when used with the CLIC absorber.

In case you are facing a similar situation in an account that uses the CLIC absorber, we recommend switching to the standard Fabius GS absorber until our new scavenger valve design has been qualified and approved.

For additional questions on this subject, please do not hesitate to contact Jens Boy at ext. 2271, or at boyj@draegermed.com.

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